

Remarks

Claims 1-2, 4-8, 10-20, 22-26, 28-37, and 39-42 are presented for the Examiner's review and consideration. Applicant believes the accompanying remarks, herein, serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §103(a) Rejection

Claims 1-2, 4-8, 10-20, 22-26, 28-37 and 39-42 were rejected under 35 U.S.C. §103(a) as being unpatentable over Haines et al. (US 5,810,827) ("Haines") in view of Mains et al. (US 4,421,112) ("Mains"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Haines

Haines discloses an apparatus comprising a number of components including a positioning apparatus, a pattern apparatus and a cutting apparatus. (C6,L38-40). More specifically, when the method and apparatus of the present invention are used in connection with resecting a distal femur, the positioning apparatus is located and aligned utilizing the intramedullary canal of the femur... (C6,L54-57). ...the cutting path 36 in the pattern plates 32 matches the profile of a femoral component of a knee prosthesis... (C8,L65-67).

Thus, Haines does not disclose alignment of a cutting guide without the use of an intramedullary device. Haines further does not disclose a cutting guide customized for a single bone.

Mains

Mains discloses "a guide assembly for use in a tibial osteotomy wherein two pairs of parallel guide pins are inserted into the tibia at a predetermined angle with respect to each other through a guide block. The adjacent surfaces of the pairs of pins are then used to precisely guide a saw by which a wedge-shaped segment of the tibia is removed." [Abstract].

...the guide block is removed by either breaking the block at a thin section between the pairs of guide bores or breaking off the projecting parts of at least one pair of the pins...

(C3,L20-24).

With respect to claim 13, the rejection states that Haines discloses a cutting guide (406) customized for a single bone, but Applicant respectfully suggests, support for this is not cited, nor found in the reference. As cited above, the reference specifically states that the pattern (cutting) guide of Haines *matches the shape of a knee prosthesis*, and is not in any way customized for a single bone.

Haines further does not disclose alignment of a cutting guide using computer navigation, preoperative imaging, or extramedullary alignment, as claimed in claim 39. Rather, Haines specifically states, as cited above, that intramedullary alignment is required for distal cuts on the femur. Mains is not directed to a knee replacement, and thus does not cure this deficiency.

The rejection further cites Mains for evidence of a disposable cutting guide. However, as discussed in detail in a previous response, Mains is non-analogous as it is not directed to knee replacements. Moreover, Applicant notes that claim 13 recites a particular feature which requires that the cutting guide of the invention be disposed, in particular, “as [the cutting guide is] no longer useful after the bone for which it has been customized has been cut and thereby changed”. In Mains, the guide may be disposed because it is perhaps difficult to remove from the installed pins. As acknowledged in the Office Action, Haines does not disclose a disposable guide. Accordingly, neither Mains nor Haines discloses the claimed feature that requires the guide of the instant invention to be disposed.

With respect to claims 1 and 19, the methods recite making an initial cut on an unresected bone. The cited portion of Haines, C20L1-16, refers to revision surgery, where the bone has previously been cut using a prior art method of alignment. Accordingly, Applicant respectfully submits that Haines does not support positioning a cutting guide using references derived independently from an intramedullary device for an unresected bone, as is claimed in claims 1 and 19.

Applicant further submits that neither reference suggests or teaches making an incision sized smaller than the portion of knee to be replaced, as is claimed in claims 1 and 19. Initially, Mains does not disclose replacing a portion of the knee. Further, Haines is not directed to minimally invasive methods. Indeed, the instrumentation in Haines appears significantly larger

than the knee (e.g. Fig's. 12 or 18), and would require complete exposure of the knee, using conventional prior art techniques. There is additionally no discussion of a reduced size incision in Haines.

Finally neither reference suggests or teaches forming an initial cut using the cutting guide. In the disclosure of Haines, the initial cuts are made to insert an intramedullary device. In Mains, notwithstanding the non-analogous nature of the disclosure, the initial cuts are made by inserting alignment pins.

Accordingly, Applicant respectfully submits that independent claims 1, 13, and 19 are patentable over Haines in view of Mains. As claims 2, 4-8, 10-12, and 31-33 depend from claim 1; claims 14-18, 34 and 39 depend from claim 13; and claims 20, 22-26, 28-30 and 35-37 depend from claim 19, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the remaining dependent claims are allowable over the cited references at least for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of this section 103 rejection.

Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fees are believed to be due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A03-012C).

Respectfully submitted,

/ Gary S. Winer /

Gary S. Winer, Reg. #31,806 for
Paul Bianco, Reg. #43,500

Customer Number: 33771
FLEIT GIBBONS GUTMAN BONGINI & BIANCO, P.L.
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605, pbianco@fggbb.com